

REMARKS

Claim Rejections 35 U.S.C. § 112

In section 2 of the Office Action, the Examiner has rejected Claim 19 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner indicates that the limitation “the bioabsorbable body” has insufficient antecedent basis. Applicant has amended the claim to correct this deficiency and requests that the Examiner withdraw the rejection.

Claim Rejections 35 U.S.C. § 102

In section 4 of the Office Action, the Examiner has rejected Claims 1-6 under 35 USC § 102(e) as being anticipated by Brucker (USPN 6,296,657). The Examiner contends that Brucker discloses each limitation of the claims, including a bioabsorbable body that does not expand when exposed to fluid and a bioabsorbable sealing member.

Applicant respectfully submits that Brucker fails to disclose a sealing member that “is disposed within the body member lumen” as required by the claims. Indeed, each figure of the Brucker disclosure shows that the sealing member extends beyond the non-expandable body. For example, Fig. 1b clearly shows element 18 in its expanded configuration extending outside the lumen of device 10 and pressing against tissue 24. Similarly, the operation of the embodiment shown in Fig. 3 is described as “balloon 32 is inflated and conforms to the vessel” and “[t]he sides of the balloon also engage the tissue near the vessel and provide a seal against the tissue surfaces.” See. Brucker, col. 4, lines 25-27.

In contrast, Applicant’s invention requires a sealing member “disposed within the body member lumen.” As emphasized in the previous response, expansion of the sealing member occurs within the body lumen member and the sealing member does not need to contact tissue to seal the passageway. To clarify this distinction, Applicant has amended the claims to specify that the sealing member does not extend outside the body lumen member. Since Brucker clearly fails

to disclose this aspect of the invention, Applicant respectfully requests that the Examiner withdraw the § 102(e) rejection of Claims 1-6.

Claim Rejections 35 U.S.C. § 103

In section 6 of the Office Action, the Examiner has rejected Claims 9 and 10 under 35 USC §103(a) as being unpatentable over Brucker as cited above. Although the Examiner concedes that Brucker fails to disclose the dimensions and ratios indicated in the claims, the Examiner states that they would be obvious design choices depending upon the intended use of the device. However, this has no bearing on the deficiency of Brucker discussed above. Since Brucker fails to disclose or suggest a sealing element having the claimed features, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of Claims 9 and 10.

With regard to section 7 of the Office Action, the Examiner rejected Claims 7-8, 19-24, 27-28, 31-35 and 37 under 35 USC §103(a) as being unpatentable over Brucker as cited above in view of Atkinson (USPN 6,645,225). The Examiner supplements the teachings of Brucker discussed above with Atkinson's disclosure of a connector of the proximal end of the body and the use of an elongate shaft. Nevertheless, Atkinson does not provide any suggestion regarding the claim limitations that require the sealing member be disposed in the plug member lumen and not extend outside the plug member lumen. Therefore, Atkinson does not compensate for the deficiencies of Brucker discussed above. Applicant has amended independent Claim 19 to require similar elements to those described above with regard to Claim 1. Since the cited combination of Brucker and Atkinson fails to disclose or suggest a sealing element having the claimed features, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of Claims 7-8, 19-24, 27-28, 31-35 and 37.

With regard to section 8 of the Office Action, the Examiner rejected Claims 11-15 and 18 under 35 USC §103(a) as being unpatentable over Hermann (USPN 5,871,474). The Examiner contends that Hermann discloses a similar device, including the non-expandable body and the sealing member. Although Hermann fails to disclose that the body member is made from a bioabsorbable material, the Examiner further contends that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a bioabsorbable material

for the body since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.”

First, Applicant respectfully submits that Hermann does not disclose or suggest the characteristics required by the claims. Specifically, Claim 11 requires that the sealing member be movable from a wide portion of the body member lumen into the tapered portion of the body member lumen to seal the lumen. Applicant notes that none of the embodiments of Hermann disclose or suggest a movable sealing member. For example, Fig. 4, cited by the Examiner, superficially appears to show balloon membrane 20 as a separate, movable member. However, Fig. 4 is identified as an exploded view and does not represent the working features of the Hermann device. Indeed, the specification clearly describes balloon member 20 as being “sealed to the skin seal funnel at the upper edge and lower edge of the balloon membrane.” See USPN 5,871,474, col. 6, lines 13-15. Therefore, Applicant respectfully submits that Hermann does not disclose or suggest a movable sealing member. Indeed, the fixed nature of Hermann’s balloon is integral to its intended function of being readily inflatable and deflatable to reversibly seal around surgical instruments inserted through the device.

Further, Applicant notes that the Hermann device is directed to the field of laproscopic surgeries and, as such, the stated purpose of the reference is to facilitate the use of normal surgical instruments in laparoscopic procedures. One of skill in the art would readily recognize that the introducers and skin seals disclosed by Hermann are relatively large and are designed to be left in the body for only the short periods of time needed to complete laparoscopic procedures. The devices are not intended to remain inside a patient, but rather are removed after completion of the procedure. Thus, there would be no reason to make them from a bioabsorbable material. Moreover, the Hermann devices must be large enough to accommodate “normal surgical instruments” and therefore represent too much mass to be bioabsorbable in practice, even if they were made of the appropriate material. Therefore, Applicant respectfully submits that a bioabsorbable material would not be suitable for the intended use of the Hermann device and one of skill in the art would have no motivation to modify the Hermann reference in the manner suggested by the Examiner.

For these reasons, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of Claims 11-15 and 18 over Hermann.

Next, with regard to section 9 of the Office Action, the Examiner rejected Claims 16 and 17 under 35 USC §103(a) as being unpatentable over Hermann as discussed above, further in view of Atkinson, as also discussed above. Atkinson is cited for its teaching of an elongate shaft and connector, but does not provide any suggestion regarding the requirements that the sealing member be movable. Moreover, Atkinson does not provide any motivation to form the body member of the device from a bioabsorbable material. For these reasons, Atkinson does not compensate for the deficiencies of Hermann discussed above. Since the cited combination fails to disclose or suggest a moveable sealing element or a bioabsorbable body, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of Claims 16 and 17.

With regard to section 10 of the Office Action, the Examiner rejected Claim 25 under 35 USC §103(a) as being unpatentable over Brucker and Atkinson as discussed above regarding section 7, further in view of Hermann for its teaching of a movable sealing member. As discussed above, Applicant respectfully submits that Hermann fails to suggest a movable sealing member. The deficiencies of the Brucker and Atkinson combination are also discussed above. For those reasons, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of Claim 25.

Next, regarding section 11 of the Office Action, the Examiner rejected Claim 29 under 35 USC §103(a) as being unpatentable over the Brucker and Atkinson references, as applied in section 7, further in view of Davis (USPN 6,143,004). The Examiner cites the Davis reference for its teaching of a second elongate member with bleed back lumen. As discussed above, Applicant submits that Brucker does not provide any suggestion regarding the requirements that the sealing member be disposed in the plug member lumen and not extend outside the plug member lumen and Atkinson does not supply the missing teachings. Since Davis also fails to compensate for these deficiencies, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of Claim 29.

Finally, regarding section 11 of the Office Action, the Examiner rejected Claim 29 under 35 USC §103(a) as being unpatentable over the Brucker and Atkinson references, as applied in

section 7, further in view of Davis (USPN 6,143,004). The Examiner cites the Davis reference for its teaching of a second elongate member with bleed back lumen. As discussed above, Applicant submits that Brucker does not provide any suggestion regarding the requirements that the sealing member be disposed in the plug member lumen and not extend outside the plug member lumen and Atkinson does not supply the missing teachings. Since Davis also fails to compensate for these deficiencies, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of Claim 29.

Allowable Subject Matter

Applicant thanks the Examiner for the indication of allowability regarding Claims 26, 30 and 36. However, in view of the amendments to the claims and remarks above, Applicant respectfully submits these claims are allowable as written.

Conclusion

Applicant respectfully requests that a timely Notice³ of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

DERGOSITS & NOAH LLP

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By: /s/ Todd A. Noah
Todd A. Noah
Reg. No. 35,626